

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)
)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

9149

Bartle, J.

September 25, 2013

Tom S. Yeary ("Mr. Yeary" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits") and, if so, whether he met his burden of proving that his claim was not based, in whole or in part, on any intentional material misrepresentation of fact.²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In October, 2002, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Dominic M. Pedulla, M.D., F.A.C.C. Dr. Pedulla is no stranger to this litigation. According to the Trust, he has signed in excess of 128 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated August 7, 2002, Dr. Pedulla attested in Part II of claimant's Green Form that Mr. Yeary

2. (...continued)

(Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.³ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$496,153.⁴

In the report of claimant's echocardiogram, Dr. Pedulla stated that claimant had moderate mitral regurgitation, which he measured at 33.5%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Pedulla also stated, "Left atrial enlargement (5.35 cm) - parasternal long axis view." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b)ii). Dr. Pedulla also measured claimant's ejection fraction to be 57%. An ejection fraction is considered reduced for purposes of a

3. Dr. Pedulla also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

4. Under the Settlement Agreement, an eligible class member is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left atrial dimension and a reduced ejection fraction are each one of the complicating factors necessary for a Level II claim.

mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b)iv).

In February, 2004, the Trust forwarded the claim for review by David B. Lieb, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Lieb concluded that there was a reasonable medical basis for Dr. Pedulla's findings that claimant had moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.

Based on Dr. Lieb's findings, the Trust issued a post-audit determination awarding Mr. Yeary Matrix Benefits. Before the Trust paid Mr. Yeary's claim, we imposed a stay on the processing of claims pending implementation of the Seventh Amendment to the Settlement Agreement. See Pretrial Order ("PTO") No. 3511 (May 10, 2004). Prior to the entry of the stay, the Trust identified 968 Matrix claims that had passed audit as payable, which were designated as "Pre-Stay Payable Post-Audit Determination Letter ('PADL') Claims." Pursuant to Paragraph 5 of PTO No. 3883, the Trust was ordered to separate the Pre-Stay Payable PADL Claims into three categories. Of the 968 Pre-Stay Payable PADL Claims, the Trust alleged that 580 claims, including Mr. Yeary's, contained intentional material misrepresentations of fact. These 580 claims are commonly referred to as "5(a) claims." See PTO No. 3883, at ¶ 5 (Aug. 26, 2004).

Following the end of the stay, we ordered the Trust to review the 580 claims designated as 5(a) claims and issue new

post-audit determinations, which claimants could contest. See PTO No. 5625 (Aug. 24, 2005). Prior to the Trust's review of Mr. Yeary's claim, on November 22, 2006, this court approved Court Approved Procedure ("CAP") No. 13, which provided 5(a) claimants with the option either to submit their claims to a binding medical review by a participating physician or to opt out of CAP No. 13. See PTO No. 6707 (Nov. 22, 2006). Mr. Yeary elected to opt out of CAP No. 13.

The Trust therefore undertook to determine whether there were any intentional material misrepresentations of fact made in connection with Mr. Yeary's claim. As part of this review, the Trust engaged Joseph Kisslo, M.D., to review the integrity of the echocardiogram system used during the performance of echocardiographic studies and the resulting interpretations submitted in support of Mr. Yeary's claim. As stated in his January 23, 2007 declaration, Dr. Kisslo determined, in pertinent part, that:

In Mr. Yeary's study, the use of color persistence and the overmeasurement of the mitral "jet," as well as the undermeasurement of the left atrial area and the overmeasurement of the left atrial dimension are the result of deliberate choices and conduct engaged in by the sonographer performing this study and at a minimum, acquiesced in by the Attesting Physician. Each of these manipulations exaggerated or created the appearance of regurgitation, jet duration or a complicating factor. Mr. Yeary has only mild mitral regurgitation.⁵

5. In November, 2004, the Trust had provided Mr. Yeary with an
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Thus, notwithstanding Dr. Lieb's findings at audit, the Trust rescinded its prior post-audit determination letter and issued a new post-audit determination denying Mr. Yeary's claim based on its conclusion that there was substantial evidence of intentional material misrepresentations of fact in connection with the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Mr. Yeary contested this adverse determination.⁶ In contest, Mr. Yeary argued that the Trust did not satisfy its burden pursuant to PTO No. 3883, Audit Rule 23, or Rule 9(b) of the Federal Rules of Civil Procedure with respect to its claim of intentional material misrepresentations of fact because Dr. Kisslo: (1) failed to explain in his declaration whether he is referring to Mr. Yeary's claim, claims in which Dr. Pedulla served as the attesting

5. (...continued)

"Expert Report" signed by Dr. Kisslo pursuant to Paragraph 11 of PTO No. 3883. In that report, Dr. Kisslo opined that claimant's echocardiogram "evidences a misrepresentation of the severity of mitral regurgitation." Dr. Kisslo explained, "I have concluded that the reliance on non-regurgitant flow and the tracing of the mitral regurgitation jet outside any color boundary resulted in a significant misrepresentation of the size of the mitral regurgitant jet so as to render it clinically unreliable. I have further concluded that the diagnosis of moderate mitral regurgitation by the Attesting Physician on this study significantly misrepresented the level of regurgitation and is beyond the bounds of medical reason."

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Yeary's claim.

physician, or all post-audit determination letters that had been issued prior to the stay; (2) used the term "color persistence," which is not defined or mentioned in the relevant medical literature; and (3) referred to "incorrect measurements and incorrect settings" without identifying the correct measurements or settings. In addition, claimant asserted that while Dr. Kisslo suggested Mr. Yeary's mitral regurgitation was not correctly measured, the court has approved "eyeballing" the regurgitant jet to assess severity. Mr. Yeary also contended that Dr. Kisslo's selection of a representative jet was inconsistent with the Weyman text, which, according to claimant, states that "the maximum jet area occurring at any point during systole is taken as the representative valve" and requires focus on "instantaneous, not cumulative, jet parameters."

Mr. Yeary further argued that the Trust cannot prove that he, or anyone involved in his claim, made any intentional material misrepresentations of fact in connection with his claim. In support, Mr. Yeary included declarations from himself, his attorney, Dr. Pedulla, and the sonographer who performed his echocardiogram, wherein they each denied any knowledge of a intentional material misrepresentation of fact relating to the performance or interpretation of claimant's echocardiogram.

In addition, claimant submitted a response of Dr. Pedulla to Dr. Kisslo's January 23, 2007 declaration. In his response, Dr. Pedulla opined that Mr. Yeary's RJA/LAA ratio is 21%, even when adjusting for overtracing of the RJA and

underestimation of the LAA. Claimant also included a declaration of Kacy Beamish, a second sonographer Mr. Yeary retained to opine on his level of mitral regurgitation. In her declaration, Ms. Beamish stated, "I reviewed the tape and advised [claimant's counsel] that in my opinion the echocardiogram did demonstrate mitral regurgitation of 20% or greater."⁷

The Trust then issued a final post-audit determination, again denying Mr. Yeary's claim. The Trust argued that Mr. Yeary misinterpreted the legal obligations under Audit Rules, and that "[t]he burden of proof remains on the Claimant throughout these proceedings" to establish that there is a reasonable medical basis in support of his claim - not on the Trust to prove that an intentional material misrepresentation of fact exists. The Trust also asserted that Mr. Yeary's contest does not satisfy this burden because, while it raised numerous contentions and criticisms pertaining to Dr. Kisslo's declaration, neither

7. Claimant also incorporated by reference a September 8, 2005 letter from Class Counsel to the Trust. In this letter, Class Counsel argued, among other things, that the Trust could not deny payment on any claim in which a post-audit determination letter had been sent unless it found that the claim was based on a fraudulent echocardiogram and that the Trust could not rely on the reports of Dr. Kisslo to determine whether a claim in which a post-audit determination letter had been sent was fraudulent. The issues raised in Class Counsel's letter also were the subject of a motion filed by Class Counsel and joined by a number of firms representing various Class Members. Class Counsel and all but one firm subsequently withdrew the motion after the adoption of certain Court Approved Procedures. We denied the motion of the remaining firm following briefing and argument. See PTO No. 6099 (Mar. 31, 2006).

claimant nor Dr. Pedulla specifically identified any alleged errors in Dr. Kisslo's findings.

In addition, the Trust contended that claimant's challenge to Dr. Kisslo's use of the term "color persistence" in his declaration was misplaced since it signifies the importance of jet duration in determining moderate mitral regurgitation, as opposed to the "isolated instances of moderately sized jets" exhibited in claimant's echocardiogram. Lastly, the Trust rejected Dr. Pedulla's representation that any overmeasurement should be viewed as an unintentional error. Instead, the Trust argued that the "jet overtracing, generally represented by tracing outside of jet borders and the inclusion of entrainment (low velocity flow)" depicted in Mr. Yeary's study were not simply "the result of random error within reasonable range," but, instead, one instance in a pattern of "distinct recurrent manipulations" that Dr. Kisslo observed in the echocardiograms performed by the company that completed claimant's echocardiogram.

Mr. Yeary disputed the Trust's final determination and requested that his claim proceed through the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Yeary's claim should be paid. On July 13, 2007, we issued an Order to show cause and referred the matter to the

Special Master for further proceedings. See PTO No. 7314 (July 13, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on November 9, 2007, and claimant submitted a sur-reply on May 8, 2008. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden of proving that there is a reasonable medical basis for Mr. Yeary's claim.⁹ Where the

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problem." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

9. Given our resolution with respect to whether there is a reasonable medical basis for the attesting physician's finding that Mr. Yeary suffered from moderate mitral regurgitation, we
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Trust's post-audit determination finds intentional material misrepresentations of fact, the claimant has the burden of proving that all representations of material fact in connection with his claim are true. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form either because of an intentional material misrepresentation of fact or some other valid reason, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers with no intentional material misrepresentations of fact made in connection with the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Yeary incorporated the arguments he made at contest. In addition, he asserts that PTO No. 3883 only "authorized non-payment of the [post-audit determination letters] in those instances where the Trust could prove there had been an '*intentional manipulation of echocardiogram tape,*'" and did not authorize a second audit of his claim (emphasis in original). Thus, Mr. Yeary contends that the Trust must first prove that there was an intentional material misrepresentation of fact in connection with his claim before we

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need not determine whether there is a reasonable medical basis for finding that he suffered from an abnormal left atrial dimension or a reduced ejection fraction.

may consider whether Mr. Yeary has a compensable level of mitral regurgitation.

In response, the Trust argues that it did not re-audit Mr. Yeary's claim. According to the Trust, Dr. Kisslo attempted to "read through" the misrepresentations in connection with Mr. Yeary's claim to determine whether they were material. The Trust also contends that the review provided for by PTO No. 3883 does not apply only to frame insertions and similar echocardiogram tape manipulations.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that it was not conducted in a manner consistent with medical standards. Specifically, Dr. Vigilante observed:

All of the usual echocardiographic views were obtained. However, the images were not conducted in a manner consistent with medical standards. There was excessive color gain with color artifact noted even within the myocardial tissue. Low velocity flow was inappropriately highlighted in this study. In addition, color persistence was noted with the inappropriate appearance of mitral regurgitation occurring during diastole during several cardiac cycles.

Despite these deficiencies, Dr. Vigilante noted that he was able to evaluate claimant's echocardiogram and determined that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Dr. Vigilante explained, in pertinent part, that:

Evaluation of the mitral regurgitation jet occurred in both the apical four chamber and apical two chamber views. The mitral

regurgitation jet appeared most impressive in the apical four chamber view. However, there was some artifact due to excessive color gain and persistence. I digitized the cardiac cycles in the apical four chamber and apical two chamber views during color flow evaluation. In spite of color artifact, I was able to accurately planimeter the RJA in several cardiac cycles. The largest RJA was 4.0 cm². This determination was made in the apical four chamber view. Most of the RJA determinations were much less than this value. The RJA was less than 3.0 cm² in the apical two chamber view. I was also able to accurately planimeter the LAA. This measurement was performed in the same cardiac cycle in which the sonographer planimetered the LAA. I determined that the LAA was 24.3 cm². Therefore, the largest RJA/LAA ratio was less than 17%. The RJA/LAA ratio never approached 20%. Therefore, I determined that, at worst, only mild mitral regurgitation was present on this study. I reviewed the sonographer's measurements on the study. Two supposed RJA's were measured by the sonographer. The measurements were 7.23 cm² and 9.42 cm². The sonographer's measurement of 7.23 cm² is inaccurate by inclusion of significant low velocity non-mitral regurgitation jet flow within this measurement. The true RJA measurement in this frame was 3.9 cm². The second sonographer's RJA measurement of 9.42 cm² is completely inaccurate. This cardiac frame is not even demonstrating mitral regurgitation and is taken in the wrong phase of the cardiac cycle. I also reviewed the sonographer's LAA measurement of 23.2 cm². This measurement was inaccurate and small as it did not include part of the postero-lateral aspect of the atrium.

In response to the Technical Advisor Report, Mr. Yeary reiterates his belief that the issue in his claim is not whether there is an appropriate level of mitral regurgitation but whether there are intentional material misrepresentations of fact in connection with his claim. He also argues that this case is

merely "a difference of opinion between experts" rather than an instance of intentional material misrepresentation of fact contemplated by PTO No. 3883. In addition, Mr. Yeary contends that the Trust did not comply with PTO No. 3883 because it did not identify, with the specificity required by Rule 9(b) of the Federal Rules of Civil Procedure, the alleged intentional material misrepresentation of fact in connection with this claim. Finally, Mr. Yeary asserts that Dr. Vigilante's findings with respect to excessive color gain should be excluded because they were raised for the first time in the Technical Advisor Report.

After reviewing the entire Show Cause Record, we find claimant has not established a reasonable medical basis for the attesting physician's finding that Mr. Yeary had moderate mitral regurgitation. In reaching this determination, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. In the context of those two documents, we previously have explained that conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation.

See Mem. in Supp. of PTO No. 2640, at 9-13, 15, 21-22, 26
(Nov. 14, 2002).

Here, Dr. Kisslo and Dr. Vigilante each found that claimant's sonographer improperly selected, traced, and measured a supposed regurgitant "jet." According to Dr. Vigilante, the first supposed RJA measured by the sonographer included "significant low velocity non-mitral regurgitation jet flow" while the second RJA measured by the sonographer was "completely inaccurate" because it was "taken in the wrong phase of the cardiac cycle" and "is not even demonstrating mitral regurgitation." In addition, Dr. Kisslo and Dr. Vigilante determined that the sonographer underestimated claimant's LAA, which artificially increased the supposed level of Mr. Yeary's mitral regurgitation. Finally, Dr. Kisslo and Dr. Vigilante found that the echocardiogram of attestation was not conducted in a manner consistent with medical standards because, among other things, the echocardiogram settings included the use of color persistence to exaggerate the appearance of mitral regurgitation.¹⁰

Notwithstanding these deficiencies, Dr. Kisslo and Dr. Vigilante determined that Mr. Yeary's echocardiogram demonstrated only mild mitral regurgitation. In addition,

10. Claimant's objection to use of the term "color persistence" because it is undefined is misplaced. In fact, the Trust provided in its final post-audit determination a detailed explanation of the term and how it applied specifically in the declaration of Dr. Kisslo.

Dr. Vigilante concluded, after a thorough review, that there was no reasonable medical basis for the attesting physician's opinion that Mr. Yeary had moderate mitral regurgitation. Specifically, he explained that "the largest RJA/LAA ratio was less than 17%" and that "[t]he RJA/LAA ratio never approached 20%."

Claimant does not substantively challenge the specific findings of Dr. Kisslo or Dr. Vigilante regarding the manner in which his echocardiogram was conducted. With respect to the manner in which his level of mitral regurgitation was evaluated, claimant, relying on declarations of Dr. Pedulla and Ms. Beamish, contends that his RJA/LAA ratio is moderate even taking into account the overmeasurement of his RJA and undermeasurement of his LAA. We disagree. Dr. Kisslo reviewed claimant's echocardiogram and determined it actually demonstrated only mild mitral regurgitation.¹¹ In addition, Dr. Vigilante reviewed the record, including Dr. Pedulla's declaration, and determined that Mr. Yeary's level of mitral regurgitation was less than 17%. In particular, Dr. Vigilante noted, "An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader

11. We reject claimant's argument that Dr. Kisslo's challenge to the way in which Mr. Yeary's RJA and LAA were measured is irrelevant because we have approved the use of eyeballing to determine the level of mitral regurgitation. We never have ruled that simply eyeballing a jet can provide a reasonable medical basis for the attesting physician's determination of moderate mitral regurgitation where, as here, the auditing cardiologist and the Technical Advisor have reviewed claimant's echocardiogram and determined it demonstrates only mild mitral regurgitation.

variability when recognizing the inappropriate conduct of the echocardiogram study."¹²

We also disagree with claimant's argument that one measurement of a maximum, instantaneous jet rather than a representative jet may form the basis for matrix Benefits. We previously have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram." Mem. in Supp. of PTO No. 6997, at 11 (Feb. 26, 2007); see also In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). "To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." See Mem. in Supp. of PTO No. 6997, at 11.

We also reject claimant's argument that the review of his claim by Dr. Kisslo constitutes an impermissible second audit. This argument ignores the plain language of the Audit Rules, which provides that the Trust must conduct a review separate from the auditing cardiologist with respect to whether there were any intentional material misrepresentations of fact in connection with a claim. Specifically, the Audit Rules state, in pertinent part, that:

12. Thus, we reject claimant's argument that this case is merely "a difference of opinion between experts."

The Auditing Cardiologist shall review a Claim in accordance with these Rules to determine whether there was a reasonable medical basis for each answer in Part II of the GREEN Form that differs from the Auditing Cardiologist's finding on that specific issue ("GREEN Form Question at Issue"). The Trust shall review a Claim to determine whether there were any intentional material misrepresentations made in connection with the Claim. The Trust may consider information from other Claims in Audit to determine the existence of facts or a pattern of misrepresentations implicating intentional misconduct by an attorney and/or physician that may warrant relief pursuant to Section VI.E.8 of the Settlement Agreement.

Audit Rule 5. Based on the findings of Dr. Kisslo, the Trust denied Mr. Yeary's claim, determining that the claim was based on one or more intentional material misrepresentations of fact.

Mr. Yeary disputed this determination and proceeded to the show cause process. We need not determine whether there was, in fact, any intentional material misrepresentation of fact in connection with Mr. Yeary's claim given our conclusion. Based on our review of the entire record, there is no reasonable medical basis for Dr. Pedulla's representation that claimant had moderate mitral regurgitation.¹³

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable

13. As we previously have stated, "[s]imply because an undeserving claim has slipped through the cracks so far is no reason for this court to put its imprimatur on a procedure which may allow it to be paid." Mem. in Supp. of PTO No. 5625 at 6-7 (Aug. 24, 2005). In this same vein, we will not ignore the findings of other cardiologists simply because a claim has previously passed audit.

medical basis for finding that he had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Mr. Yeary's claim for Matrix Benefits.